

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gerry Gressel on 11/25/2009.

The application has been amended as follows:

Claim 1

A biopsy device comprising:

a hollow biopsy needle having a tissue receiving port;

a hollow cutter advanceable within the biopsy needle to sever tissue received within the tissue receiving port, wherein the cutter has a sidewall surrounding an interior, wherein the cutter has a plurality of holes spaced from the distal end of the cutter, wherein the plurality of holes are formed transversely through the sidewall of the cutter for providing fluid communication from a region exterior to the sidewall of the cutter to the interior of the cutter, and wherein the holes are positioned for providing vacuum axially through the cutter when multiple tissue samples are disposed within the a sample tube within the cutter; and

~~a~~the sample tube advanceable within the hollow cutter, the sample tube having an open distal end sized for receiving a tissue sample severed by the hollow cutter the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue

Art Unit: 3736

sample stored therein may be removed from the biopsy device without disassembling the biopsy device, ~~and~~ wherein the sample tube comprises a vacuum lumen and a sample lumen, ~~and~~ wherein the vacuum lumen extends along side of at least a portion of the sample lumen ((.)) ,

wherein the hollow cutter is operable to be advanced to a distal most position within the hollow biopsy needle to sever the tissue sample, and

wherein the sample tube is operable to be advanced to the distal most position within the hollow cutter to receive the tissue sample after the tissue sample has been completely severed.

Claim 7

The biopsy device of Claim 1 comprising an apparatus for advancing and retracting the cutter within the biopsy needle.

Claim 8

The biopsy device of Claim 7 comprising an apparatus for advancing and retracting the sample tube within the cutter.

Claim 16

A biopsy device comprising:

a hollow biopsy needle having a closed distal end and a lateral tissue receiving port spaced proximally of the closed distal end;

a hollow cutter having an open distal end, a lumen extending proximally from the open distal end, and a plurality of holes extending through a wall of the cutter; ~~and~~ the the cutter

advanceable to a distal most position within the biopsy needle to sever tissue received within the tissue receiving port;

a sample tube having an open distal end defining a distal opening, the sample tube being releasably supported on the biopsy device, and the sample tube advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle((,)) ;
and

a sample tube advancement assembly, wherein the sample tube advancement assembly is operable to advance the sample tube ~~distally~~ to the distal most position within the cutter to store a tissue sample within the sample tube after the cutter has been advanced within the needle to the distal most position to sever the tissue sample ((,)) ; wherein the sample tube comprises a vacuum lumen and a sample lumen, and wherein the vacuum lumen extends along side of at least a portion of the sample lumen.

Claim 17

A method of obtaining a tissue sample comprising the steps of:

drawing tissue into a side tissue receiving port of a hollow biopsy needle;

advancing a hollow cutter in the needle to sever a tissue sample and to encapsulate the severed tissue sample within the cutter upon reaching a distal most position in the hollow biopsy needle, wherein the cutter closes the tissue receiving port when the cutter is at the distal most position;

advancing a hollow sample tube to the distal most position in the cutter to position the tissue sample in the sample tube, wherein the hollow sample tube has an open distal end, wherein

Art Unit: 3736

the open distal end comprises a distally facing opening defined by the distal most perimeter of the open distal end, wherein the tissue sample is axially received in the hollow sample tube through the opening at the open distal end of the hollow sample tube during the act of advancing the hollow sample tube, wherein at least a portion of the act of advancing the hollow sample tube is performed after the cutter has reached the distal most position and after the cutter has encapsulated the severed tissue sample; and

wherein the sample tube comprises a vacuum lumen and a sample lumen, wherein the vacuum lumen extends along side of at least a portion of the sample lumen;

and wherein the method comprises providing vacuum to the sample tube vacuum lumen.

Claim 23

A needle assembly comprising a hollow biopsy needle having a closed distal end having a tissue piercing tip and a side tissue receiving port spaced proximally of the closed distal end, a cutter lumen, and a vacuum lumen, and wherein the needle comprises an axially extending slot positioned proximal of the side tissue receiving port, the axially extending slot communicating between the cutter lumen and the vacuum lumen;

a hollow cutter advanceable within the biopsy needle to sever tissue received within the tissue receiving port, wherein the cutter has a sidewall surrounding an interior, wherein the cutter has an open distal end and plurality of holes spaced from the distal end of the cutter, wherein the plurality of holes are formed transversely through the sidewall of the cutter for providing fluid communication from a region exterior to the sidewall of the cutter to the interior of the cutter;
and

a sample tube advanceable within the hollow cutter, the sample tube having an open distal end sized for receiving a tissue sample severed by the hollow cutter, the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device; and

a vacuum source operable to communicate vacuum through the sample tube ((.)) ,
wherein the hollow cutter is operable to be advanced to a distal most position within the hollow biopsy needle to sever the tissue sample, and
wherein the sample tube is operable to be advanced to the distal most position within the hollow cutter to receive the tissue sample after the tissue sample has been completely severed.

Also, please cancel **Claim 19**.

2. The following is an examiner's statement of reasons for allowance: the prior art does not teach or suggest alone or in combination a biopsy device comprising a hollow biopsy needle, a hollow cutter, and a hollow sample tube, wherein the hollow cutter is operable to be advanced to a distal most position within the hollow biopsy needle to sever the tissue sample, and wherein the sample tube is operable to be advanced to the distal most position within the hollow cutter to receive the tissue sample after the tissue sample has been completely severed.
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

Application/Control Number: 10/732,843
Art Unit: 3736

Page 8